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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,587	06/24/2005	Akiko Nishi	12218/42	5532
23838	7590	02/07/2006	EXAMINER	
KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			WALICKA, MALGORZATA A	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/516,587

Applicant(s)

NISHI ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/03/05</u> . | 6) <input type="checkbox"/> Other: ____. |

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The application, filed Jun 24, 2005, is a national stage of the PSCT/JP03/06807. Claims 1-38 are pending and under examination.

DETAILED ACTION

1. Priority

Acknowledgment is made of applicants' claim for priority based on an application number 2002-165722 filed in Japan on 06/06/2002. Applicants filed the priority document, however it is not translated. SEQ ID NO: 1 and 2 are disclosed in the priority document, as well as drawings presenting data for wild type acylase set forth by SEQ ID NO: 2. The Japanese application does not seem to disclose mutated SEQ ID NO: 2 and effects of mutation, which are only shown in PCT/JP03/06807. In result claims 4, 5, 6, 7, 11-19, 21, 22, 25-38 are entitled only to the priority date of filing of the PCT/JP03/06807 application, which is May 30, 2003.

2. Objections

2.1. Specification

The years of deposits cited on page 15 second paragraph are not translated from Japanese into Gregorian calendar.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

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2.2. Claims

Claims 8-9, 11, 12, 13, 14, 15, 16 and 17 are objected to for the use of the term "base" instead of nucleotide. Please correct.

3. Rejections

3.1. 35 USC section 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1-9, 11-27, 29-30 and 34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter; *Diamond v. Chakrabaty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated and purified protein or nucleic acid". It should be noted that a recombinant enzymes/proteins are assumed to be identical to those produced naturally unless otherwise indicated.

Claim 10 is rejected is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is directed to a product of nature, as being directed to a microorganism which produces a protein comprising an amino acid sequence being substantially identical with the amino acid sequence shown

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under SEQ ID NO: 2, wherein said microorganism belongs to the genus under *Stenotrophomonas*. Any microorganism belonging to the genus *Stenotrophomonas* is a product of nature, unless it is specifically modified by one having skills in the art. In the instant case the claim does not state that the microorganism was engineered by man.

Claim 28 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is directed to a transformant obtainable by transforming a host with the vector comprising beta-lactamase. The scope of the claim includes a transformed human being.

3.1. 35 USC, section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 4-8, 14-16, 18-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4-7 and 12-15 are confusing because they do not state that the claimed gene encodes a protein comprising SEQ ID NO: 2, wherein this sequence was modified at residue 204, or at plurality of amino acid residues.

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Claim 8 and 16 are confusing. For examination purposes it is assumed that the claims are directed to a gene, or polypeptide, which comprises DNA of SEQ ID NO: 1 encoding the amino acid sequence of SEQ ID NO: 2.

Claim 9, 18, 24 and 25 are rejected as depending on any of rejected claims 3-8 and 11-14 and 15.

Claims 20-23 are confusing. The claims do not state that the claimed protein comprises SEQ ID NO: 2, which was modified at residue 204, or at plurality of amino acid residues.

Claim 26 is unclear, because it does not state that the transcription and/or translation regulatory sequences of said regulon are substituted by other transcription and or translation regulatory sequence from the same organism or different living organism.

Claims 27 is rejected as multiply dependent. In addition, the claim is rejected as depending on rejected claims 3-9. The claim is also unclear because it is unknown whether the Applicants' invention is the vector that comprises only one of the genes of the recited claim as opposite to many copies or applicants refer to the gene meaning the claim in which said gene is claimed.

Claims 28-33 are rejected as depending on claim 27, which is a multiply dependent claim. In addition, even if claim 27 is not multiply dependent, the claims depend on the rejected claims 3-9.

Claim 34-38 are rejected as being multiply dependent.

Furthermore, claim 35 directed to an immobilized cell disrupted product. The composition obtained by cell disruption contains many products and it is unclear which product after immobilization contains beta-lactam acylase.

2.2. 35 USC, section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2.1.1. Lack of written description

Claim 1, 3, 5-7, 9,10, 11, 13, 14, 15, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28-30, 33, 34, 35, 36-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 31 and 32 are rejected, because the invention appears to employ novel *E. coli* transformants. Since the transformant are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be

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readily available to the public. The enablement requirements of 35 U.S.C. section 112 may be satisfied by a deposit of the transformants. The specification does not disclose a repeatable process to obtain the vectors used for obtaining transformants and it is not apparent if the DNA sequences involved are readily available to the public. Accordingly, it is deemed that a deposit of these transformants should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have deposited the organisms but there is no indication in the specification as to public availability. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strains will be available to the public under the conditions specified in 37 CFR 1.808, would satisfy the deposit requirement made herein.

Claim 1 is rejected as directed to large genus of beta-lactam acylases from a microorganism belonging to the genus *Stenotrophomonas*. The claim suffers from lack of written description of structure. Applicants teach beta-lactam acylase from *Stenotrophomonas maltophilia* KNK12A set forth by SEQ ID NO: 2. Having at hand one species of the claimed genus is not sufficient for structural identifying all species within the genus, because a change of even one amino acid in the sequence can change the catalytic activity of the protein. This fact is well known to those skilled in the art. Given the lack of structural characteristics of additional representative species as encompassed by the claim, Applicants have failed to sufficiently describe the claimed

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invention in such full, clear, concise and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention when the application was filed.

Claims 5, 6, 7, 9, 10, 13, 14, 15, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 30, 33-38 are rejected for lack of written description of structure and/or function or for a total lack of written description.

Claims 5 and 19-21 does not state that the claimed mutants should have the desired function of beta-lactam acylase.

Claims 6, 14 and 22 state the function, but are lacking written description of structure. Applicants do not teach the structure /function relationship of SEQ ID NO: 2 and its encoding sequence which is a gene/polypeptide of SEQ ID NO: 1. Applicants do not teach which plural changes of amino acids sequence of SEQ ID NO: 2, such as deletions, substitutions, or additions, are neutral from the point of view of the protein activity.

Claim 9, 10 and 18 are rejected as lacking description of structure and/or function of the claimed gene and/or the microorganism of the genus *Stenotrophomonas* from which said gene is to be obtained. The claims is directed to a large genus of genes, but Applicants teach only two species which are SEQ ID NO: 1 from *Stenotrophomonas maltophilia* KNK12A or SEQ ID NO: 1 with guanine in position 735, which means that codon 204 is for valine instead for methionine. Although the specification teaches on page 10 six species of *Stenotrophomonas*, the specification fail to teach any beta-lactam acylase gene obtained from species other than *maltophilia* KNK12A. Applicants

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also have not provided the structure of any gene that is described by one or plurality of amino acid deletions substitutions, or additions to SEQ ID NO: 2.

Claims 7 and 15 are rejected for a total lack of written description.

The claims 7 and 15 are rejected because the specification does not teach that protein of SEQ ID NO: 2 is a subject of any posttranslational modification. On page 12 of the specification Applicants exemplifies the meaning of the term "modification after translation" as referring to an enzymatic cleavage off of the 20 N-terminal amino acids which serve as signal sequence required for a move of protein to a periplasm region of microorganism. However, Applicants do not teach any N-terminal region of SEQ ID NO: 2 that is not necessary for its catalytic activity and is cleaved off posttranslationally.

Claims 24-25 are directed to a gene, which contains a transcription or/and translation regulatory sequences contained in the gene according to any of claims 3-9. The claims suffer from a total lack of written description of structure of the claimed genera of sequences. Applicant teach on page 14, last paragraph, only one transcription regulatory sequence containing 100 bases upstream from the 125th position in SEQ ID NO: 1 of *Stenotrophomonas maltophilia* KNK12A, i.e. nucleotides 24-124 of SEQ ID NO: 1. This only species of the transcription regulatory sequence disclosed by Applicants does not provide an identifying structural characteristics of the whole broadly claimed genus. It is furthermore suggested to include the structural limitations of the transcription regulatory sequence in the claims. Applicants also fail to identify the structure of the genus of translation regulatory sequences which are broadly claimed. The specification discloses only that translation regulatory sequence is a

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sequence containing 50 upstream site from the 125th in SEQ ID NO: 1, i.e., nucleotides 75 –124 of SEQ ID NO: 1; see the first line on page 15. Providing this description of sequences containing nucleotides 75-124 is not sufficient for structural identification of any transcription regulatory sequence from any species *Stenotrophomonas*.

Claim 26–30 and 33-38 are rejected as depending on any of rejected claim 3-9 or 11-18.

In addition, claim 35 is rejected because of lack of written description of how to immobilize any cell disrupt product from any *Stenotrophomonas* so that it contains an immobilized beta- lactam acylase.

For all the above explained reasons Applicants have failed to sufficiently describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention when the application was filed.

2.2.2. Scope of enablement

Claim 1, 3, 5, 6, 7, 9, 10, 13, 14, 15, 18, 19, 21, 22, 23, 24, 25, 27-30, 33- 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

- a) a DNA molecule of SEQ ID NO: 1 encoding beta-lactam acylase from *Stenotrophomonas maltophilia* KNK12A,
- b) beta-lactam acylase of SEQ ID NO: 2 from *Stenotrophomonas maltophilia* KNK12A,

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- (c) Met204Val mutant of beta-lactam acylase of SEQ ID NO: 2 from *Stenotrophomonas maltophilia* KNK12A
- (d) transcription regulatory sequence consisting of nucleotides 24-124 of SEQ ID NO: 1,
- e) translation regulatory sequence consisting of nucleotides 75 –124 of SEQ ID NO: 1,
- (f) immobilized beta-lactam acylase of SEQ ID NO: 2,
- (g) a recombinant method of producing beta-lactam acylase of SEQ ID NO: 2 or its improved mutant Met204Val, and
- (h) a method of producing a beta-lactam antibiotic by using beta-lactam acylase of SEQ ID NO: 2 or its improved mutant Met304Val,

does not reasonably provide enablement for

- (A) a beta lactam acylase produced by any microorganism belonging to the genus *Stenotrophomonas*,
- (B) a DNA molecule coding for a protein comprising any amino acid sequence substantially identical to SEQ ID NO: 1 or protein that is substantially identical to SEQ ID NO: 2,
- (C) any polynucleotide/gene which encodes a protein comprising an amino acid sequence in which one or a plurality of amino acids in the amino acid sequence shown under SEQ ID NO:2 have undergone deletion, substitution or addition and having beta-lactam acylase activity or protein having these features,

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- (D) polynucleotide (B) or (C) wherein said polynucleotide is isolated from a microorganism belonging to *Senotrophomonas*,
- (E) a gene containing a transcription or translation regulatory sequence wherein said sequence are contained in the modified genes /polynucleotides of SEQ ID NO: 1, and
- (F) immobilized cell, mixed cell culture and cell disrupted product.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the inventions commensurate in scope with these claims.

The scope of the claim must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)), otherwise, making and/or using the invention requires additional experimentation.

The factors to be considered in determining whether undue experimentation is required to make the invention are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)].

The scope of the claims covers a large and variable genus of DNA molecules, and proteins, mentioned at (B), (C), (A) and (D) and for that matter expression vector and transformed cells, as well as methods of recombinant production of said proteins, as well as processes of using of said proteins for production of beta-lactam antibiotics, wherein the guidance for structure of polynucleotides and proteins mentioned at (B), (C), (A) and (D) is clearly lacking.

While enablement is not precluded by the necessity for routine screening, if a

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large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed so that the claimed species have the functionality of beta-lactam acylase. The provision of SEQ ID NO: 1 and 2 and the mutant substituted in amino acid residue 204 of SEQ ID NO: 2 fails to provide such guidance of polynucleotides and polypeptides with major structural variations therefrom which remain encompassed within the scope of the

rejected claims. The polynucleotides and polypeptides are from any natural source, man-made or from any species of the genus of *Stenotrophomonas*. Applicants attention is turned to the fact that defining the sequence "As substantially identical wherein the sequence is 80% or 90% identical to SEQ I ID NO: 2 is not an identification structural characteristics absent teaching how to modify SEQ ID NO: 2 so that it still possesses the required activity of beta-lactam acylase. Providing mutation in position 204 is not instructive for the claimed major structural changes that are neutral for the activity of beta-lactam acylase.

Regarding point (E) related to claim 24 and 25, the nature and the breath of invention is so broad as to cover many natural or man-made genes because it covers the structure of transcription and translation regulatory sequences, which are any fragments from a large genus of genes. When claims 24 and 24 depend on claim 3 structural limitation "substantially identical" means 80% -90% identity, which involves many changes in SEQ ID NO: 1 all of them, or part of them, may be in the regulatory sequences. When claims 24 and 25 depend on claim 6 the structure of SEQ ID: 1 is

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profoundly modified to the extent that it is not SEQ ID NO: 1 anymore and its regulatory sequences stop to be regulatory sequences or are regulatory sequences from any other gene. In results, the scope of regulatory fragments is enormous because it covers a transcriptional and translational regulatory fragment from any gene. Teaching the structure of SEQ ID NO: 1 does not provide sufficient guidance to make any gene out of their astronomical number. Without a further guidance as to the structure of transcription and translation regulatory sequence to be encompassed by the gene, Applicants force a skilled artisan to perform experimentation that has an extremely low probability of success and thus is undue.

Regarding point (F), related to claim 45, the scope of the claim cover an enormous number of cell, cell mixed culture and products obtained by disruption of a cell wherein all cells cell mixed culture and said products are immobilized.

Immobilization of cell is dependent on its species. Immobilization of a mixed cell culture, or just culture is impossible. As to the products of disruption, said products comprise any protein, lipid, nucleic acid sugars or compositions thereof. Applicants provide enblement for immobilization of beta-lactam acylase. This is however not sufficient for enablement of immobilization of any cell or any cellular product obtained by cell disruption, as broadly claimed by Applicant. In result, experimentation left to those skilled in the art is extensive and undue.

In addition, claims 28 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for host cells transformed with the claimed gene and polynucleotides, does not reasonably provide enablement for all possible host

organisms similarly transformed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Furthermore claim 28 is specifically rejected because its scope encompasses all multicellular organisms transformed said DNA molecules. The specification, however, only describes the transfection of host cells. Despite knowledge in the art of transformation techniques and the production of transgenic organisms, the specification fails to provide guidance regarding what organisms would be expected to tolerate expression of the heterologous enzymes encoded by the DNA molecules. It remains *a priori* unpredictable as to the result of systemic expression of the several heterologous enzymes during growth and development of complex multicellular organisms. The use of regulated promoters is insufficient because of the fact that they remain "leaky" and allow low levels of expression. In the absence of information regarding the effects of systemic expression of the disclosed proteins in complex multicellular organisms, it is unpredictable as to what transgenic multicellular organisms can be produced with DNAs encoding these proteins. Lastly, while recombinant techniques are available, it is not routine in the art to attempt large numbers of transgenic complex multicellular organisms, where the expectation of successful transformation/transduction is unpredictable based on the instant disclosure. Therefore, one of ordinary skill would require guidance, in order to make and use host organisms in a manner reasonably commensurate with the scope of the claim. Without such guidance, the experimentation left to those skilled in the art is undue.

2.2.3. *Lack of enablement*

Claim 7, 15 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 7, 15 and 23 are directed to a gene/polynucleotide, encoding polypeptide containing or being SEQ ID NO: 2 wherein SEQ ID NO: 2 is modified after translation. The claims completely lack the enablement because SEQ ID NO: 2 is not disclosed by Applicants as being posttranslationally modified to be enzymatically active. Therefore, making the claimed invention imposes on the skilled artisan an undue experimentation that has a zero probability of success.

2.3. **35 USC section 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 6, 14, 22, 26, 27, 29 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,168,048, issued Dec. 1, 1992, included in the Information Disclosure Statement.

The claims are directed to a gene, a polynucleotide and a protein encoding beta-lactam acylase activity, wherein said protein is an amino acid sequence comprising SEQ ID NO: 2 in which a plurality of amino acids have undergone deletion, substitution or addition. The claims read on any beta lactam acylase and encoding polynucleotide or gene.

The patent discloses a gene encoding beta-lactam acylase, and the protein, from *Alcaligenes faecalis*, see SEQ ID NO: 1. The patent discloses a beta-lactam acylase having the limitations of claims 6, 14, and 22.

In addition, claim 26 is rejected because it claims the same invention as that of claim 3 of the patent. Claim 3 of the patent recites the gene encoding penicillin G acylase from *Alcaligenes faecalis*. The gene, as stated above, anticipates the gene of claim 6 of the instant application.

Furthermore claim 27 of the instant application is rejected as directed to a vector comprising the gene of claim 6 of the instant application, as anticipated by the vector of claim 4 of the patent.

Claim 29 of the instant application claims the same invention as that of claim 7 of the patent.

Claim 22 is rejected over the beta-lactam acylase of the patent as directed to any beta-lactam acylase that can be derived from SEQ ID NO:2 in which a plurality of amino acids have undergone deletion, substitution or addition.

Claim 34 of the instant application is rejected because it is directed to a beta-lactam acylase encoded by a polynucleotide of claim 15. Thus, the claimed beta-lactam acylase is the same invention as that taught by the patent.

3. Conclusion

No claim is in condition for allowance, however the claims contain allowable subject matter. The following is the examiner reason for indicating allowable subject matter. No prior art teaches or fairly suggest the beta-lactamase set forth by SEQ ID NO: 2, its mutant containing in position 204 valine, as well as the encoding gene /polypeptide set forth in SEQ ID NO:1. The enzyme is useful in production of antibiotics, particularly of amoxicillin.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Patent Examiner



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